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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/415,890	10/08/1999	BORJE S. ANDERSSON	UTXC:528--1	5425

7590 03/18/2002

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EXAMINER

LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Art Unit: 1616

Receipt is acknowledged of ~~CA~~ and amendment (12/21/01).

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 69-87 been renumbered 81-99 respectively.

Claims 16-23, 49, ~~60~~⁸⁰-80, 83, 92, ~~99~~ are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

Lyophilized products are not solvents; they are solids, so withdrawn. As this continuation is an RCE, applicant cannot switch inventions; thus the examiner is of the solvent vehicle, not the method of making, or of the drug compositions. Applicant writes as if non-elected claims have been cancelled. They have not, but of course, applicant could do so. Claims 16-23 and 26-99 are currently pending.

Claims 26-48, 50-67, 81, 82 and 84-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The invention as now amended, as an RCE has become in essence as composition of drug and vehicle, as there is no separation of the drug from the vehicle

discernible in the claim language as supported in the specification. Applicant's identification of support does not so far as examiner can determine, provide this separation we have a different invention; that of 6045885.

Claims 26-48, 50-68, 81-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention as is now claimed is a vehicle; but the process of providing the vehicle does not exclude the drug. Examiner fails to find the process of providing, in spite of applicant's identification of support, the vehicle, the instant claim, made without the drug; thus the claim to a vehicle is beyond the scope of the specification.

Claims 82, 84-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"virtually" is seen, as supported in the specification, to include as much as 50%—this is contrary to normal usage. Applicant should identify how much is eliminated, or how much remains.

In claim 84, C is not identifiable as a composition per se in claim 26—so it is unclear what it is that's reconstituted, and what that has to do with the original vehicle solvent—do we now have 2 compositions?

Claims 26-28, 30-34, 41-45, 47, 48, 50-59 and 63-67, 81, 82, 84-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson-5559148 or 5430857.

No weight is given to the process of preparing the vehicle, as the vehicle preparation, absent drug, has NOT been shown by applicant to provide any critical or different properties as a function of the preparation, over prior art vehicles.

The rejection of record is maintained.

Now, only an aqueous vehicle is required to meet the claims (free of organic solvent).

Claims 26-27, 29, 32, 34-35, 37-42, 47, 48, 63-67, 81, 82, 84-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Sugiyama et al 5651991.

The rejection of record is maintained.

Claims 26-48, 50-67, 81, 82, 84-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al 5430057 in view of Sugiyama.

The rejection of record is maintained.

Claims 26-28, 30, 34, 36, 41, 47, 48, 52, 63-67, 81, 82, 84-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Szoka et al 5277914.

See col. 3, 4, 5, lipids and aqueous (lower alcohol) co-solvents are used as vehicles for drugs.

The rejection of record is maintained.

Claims 26, 30, 34, 42, 63-65, 67, 81, 82, 84-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Pallado et al WO 96/29998.

The rejection of record is maintained.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday-Friday 7 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Levy:mv

January 16, 2002



NEIL S. LEVY
PRIMARY EXAMINER